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59th Medical Wing
Institutional Animal Care and Use Committee (IACUC)
59 Clinical Research Division/SGVUS
1100 Wilford Hall Loop, Bldg 4430
Lackland AFB, TX 78236-5300

NOTICE OF ACTION REGARDING IACUC REVIEW

Date: 2 Mar 18

TO: Maj Joseph Maddry/SGO3D

Your **Final Report** was reviewed by the WHASC IACUC during the 13 Feb 18 meeting. The Committee's decision is provided below:

FWH20150048A, "Hydroxocobalamin for uncontrolled hemorrhagic shock resuscitation in swine (Sus Scrofa)." **PI: Maj Joseph Maddry/59 EMDS/SGO3D**

The committee voted that this item be **approved** as written. **FOLLOW-UP: CLOSED**

Name of Official
MARIA E. DOMINGUEZ

Title/Office Symbol/Phone
Office of Research Protocol Support /SGVUS 292-6095

Signature

Info Copy To

1. Protocol Number: FWH20150048A

2. Type of Research: Animal Research

3. Title: Hydroxocobalamin for uncontrolled hemorrhagic shock resuscitation in swine (Sus Scrofa)

4. Principal Investigator (PI):

Name	Rank	Date of IACUC Training	Branch of Service/ Corps	Staff Resident Fellow Civilian	Department / Office Symbol	Email (if other than WHASC Outlook)	Phone	Pager
Joseph Maddry	O-4	July 2015	USAF	Staff	59 EMDS / SGOED	Joseph.maddry@gmail.com	WP: 292-3908 FAX: 292-7649	Cell: 275-3794

5. Purpose: To determine if hydroxocobalamin, a portable, safe and FDA approved drug, is effective in improving uncontrolled hemorrhagic shock and if it will improve systolic blood pressure in an uncontrolled hemorrhagic model without generating a rebleed with equal efficacy to Hextend®.

6. Results: For the primary aim, there were no significant differences among the groups with regard to post treatment blood loss or total blood loss. Hextend was not superior to HOC. Post bleed MAP (~ 40+/- 1 mmHg) at which treatment occurred was not significantly different among the groups. There were some differences in hemodynamic variables (secondary aims) overtime. At end of study, MAP, HR, SVO2 and lactate were not significantly different, however CO and SVR were significantly different. HOC increased SVR and concomitantly decreased CO compared to Hextend.

7. How may your findings benefit the Air Force?

Hydroxocobalamin could be a useful adjunct to hemorrhagic shock in prehospital, tactical situations. It is a small volume, small weight, safe, FDA approved drug that also reduces inflammation and is neuroprotective.

8. Number of Animals

Projected Enrollment of Animals at the Beginning of Study: 46 (8 animals added through amendments 4&6 for total authorized = 54)

Actual Number of Animals Enrolled: 52

9. Status of Animals Entered Into the Protocol: All animals used were in good health.

10. Number of Animals Entered into the Study:

	Number enrolled since last report	Total enrollment to date
Number of animals entered into the Study	14	52

11. Status of Funds: All funds have been allocated, no budget deviations.

12. Reason for Closure:

Objectives of the study were met.

13. Specific Problems:

Animals 8143 & 8818 had arrhythmias during line placement and vital signs crashed. Animals were replaced via amendments 4 & 6.

14. Publications and Presentations:

Presentations:

Investigation of Intravenous Hydroxocobalamin Compared to Hextend for Resuscitation in a Swine Model of Uncontrolled Hemorrhagic Shock : A Preliminary Report. Society of Academic Emergency Medicine ; May 16-19, Orlando FL

Investigation of Intravenous Hydroxocobalamin Compared to Hextend for Resuscitation in a Swine Model of Uncontrolled Hemorrhagic Shock : A Preliminary Report. SAMHS and Universities Research Forum; University of Texas at San Antonio; June 16, 2017

Investigation of Intravenous Hydroxocobalamin Compared to Hextend for Resuscitation in a Swine Model of Uncontrolled Hemorrhagic Shock : A Preliminary Report. Military Health System Research Symposium; Kissimmee, Florida; Aug 27-30 2017

These Presentations have been cleared by 59 CRD and Public Affairs.

Publications: None

These Presentations and Publications have been cleared by 59 CRD and Public Affairs.

15. Exceptional Achievements: None

16. Signature of Principal Investigator:

Joseph Maddry, MD
Maj, USAF, MC, FS
Emergency Physician/Medical Toxicologist
Director USAF En route Care Research Center
Director, Clinical Research, Emergency Sciences and Toxicology
59th MDW/ST Chief Scientist Office
U.S. Army Institute of Surgical Research